REMARKS

According to the Office Action of February 25, 208, claims 16, and 20-39 were examined and have been rejected under 35 U.S.C. § 112, second paragraph, § 112, first paragraph, and § 103. In response, Applicants submit this Amendment, which amends claims 16, 27, 30, and cancels claim 31. No new matter has been added by these amendments. In view of the amendments to the claims and remarks below, Applicants respectfully request that the rejections be reconsidered and withdrawn.

Rejection under 35 U.S.C. § 112, Second Paragraph, Indefiniteness

Claims 16, 20-26 and 31-39 have been rejected under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point-out and distinctly claim the subject matter which the Applicants regard as the invention. Particularly, these claims were rejected under this section for the recition of "and/or human immunodeficiency virus infection" in claim 16. This recitation has been deleted from claim 16. Therefore, withdrawal of this rejection is respectfully requested.

Rejection under 35 U.S.C. § 112, First Paragraph, Enablement

Claims 16, 20-26 and 31-39 have been rejected under 35 U.S.C. § 112, first paragraph. On page 3, the Office Action acknowledges that the specification enables one skilled in the art to make and use a treatment of immune system-related disorders, but that the specification does not enable one of ordinary skill in the art to prevent immune system-related disorders.

When asserting an enablement rejection, a reasonable explanation as to why the claims are not enabled by the specification must be set forth. *In re Wright*, 999 F.2d 1557, 1561-1562 (Fed. Cir. 1993); *In re Stoughton*, No. 2005-2235, App. No. 09/038,894, 2006 WL 1665412 at *4 (BPAI 2006). Precise predictability is not the standard to employ. *In re Corpet*, No. 2004-1790, App. No. 09/836,971, 2004 WL 2733634 (BPAI 2004).

In *Corpet*, the examiner rejected claim 12 as not enabled by the specification. 2004 WL 2733634 at *1. Claim 12 recited "[a] method of preventing colon or rectum cancer comprising administering to a mammal a therapeutically effective amount of a non-fermented osmotic polyol laxative." Id. The rationale for rejecting claim 12 was based on the argument

> that the recitation of preventing "extend[s] the treatment to those patients in which rectal and colon cancers may occur at any point of time in [the] future." [Citation omitted.] With respect to the state of the art, the examiner apparently recognizes that "[t]he state of the art recognizes that increased intake of dietary fibers contribute to the increased bowel movements and thus result in lowering the risk of colon cancers," but asserts that "the art does not teach or recognize a complete prevention of the above claimed cancers." [Citation omitted.] Finally, with respect to guidance of the specification and examples, the examiner focuses on the lack of teaching of an understanding of when the cancer may occur.

Id. at *1. The Board determined that the examiner's rationale required "precise predictability as to the time when the colon or rectal cancer will appear, and also appears to require 100% prevention. That is not, however, a requirement under 35 U.S.C. § 112, first paragraph." *Id.* at *2. Due to this flawed rationale, the Board held that the examiner failed to meet his burden and reversed the rejection. *Id.* at *3.

The Board reversed a similar rejection in *In re Goldenberg*, App No. 08/183,381, 2002 WL 31105508 (BPAI 2002). In *Goldenberg*, the examiner argued that "'[a]pplicant broadly claims an anti-idiotype vaccine to prevent cancer, AIDS and malaria, but the specification fails to enable the vaccine(s) and effectively teach how to make and/or use said vaccines to achieve this.'" *Id.* at *3. The Board held that this

> failed to provide the evidence necessary to demonstrate that appellants' disclosure does not enable their claimed invention. While some of the claimed combinations may be inoperative, the examiner failed to establish that the number of inoperative combinations is so significant, that one of ordinary skill in the art would have to experiment unduly in order to practice the claimed invention.

Id. at *4. Like *Corpet*, the Board in *Goldenberg* reversed the rejection because the examiner required 100% predictability, which is not the standard for enablement.

As evident from these cases, there is no *per se* bar against claims directed to preventing a condition. Thus, there must be some evidence proffered that preventing the recited allergies is unpredictable. A non-enablement argument cannot be supported without citing some evidence. Like the rejections in *Corpet* and *Goldenberg*, this rejection does not offer the required evidence.

Moreover, like *Corpet*, there is sufficient evidence for one of ordinary skill in the art to conclude that the recited invention prevents cancer. In *Corpet*, the examiner recognized that "state of the art recognizes that increased intake of dietary fibers contribute to the increased bowel movements and thus result in lowering the risk of colon cancers.'" *Id.* at *1. Likewise, in this case, the specification admittedly enables the treatment of allergies. This, in turn, is recognized within the art as a means of lowering the risk and preventing the recited allergies.

On page 5, the Office Action contends that the Applicants have not provided a description of how allergies can be prevented. However, the Applicants have stated that the invention prevents allergies by maintaining or restoring the Th1/Th2 balance (specification at page 4, lines 1-3). Therefore, Applicants have provided, at least in theory (which Applicants do not intend to be bound by), a description of how allergies can be prevented.

On page 6, the Office Action contends that the specification does not provide working examples sufficient to support the prevention of the recited allergies. However, page 28 of the specification provides that

> administration of a combination of 1 wt. % GT and 1 wt. % AcOl resulted in a decrease in the Th2-related cytokines IL-4, IL-5 and IL-10, while the Th1-related cytokines IL-2 and IFN-γ were not lowered .... These results are indicative for the Th1/Th2 balancing effect of a combination of acid- and neutral oligosaccharides and indicative for the advantageous use of acid oligosaccharides in the present method, e.g. for the treatment and/or prevention of diseases with relatively low Th1 immunity. Particularly the IL-4/IFN ratio reflects the Th2/Th1 balance. In other words, a lower ratio is indicative for stimulation of Th1 and/or inhibition of Th2, and in any case indicative for the Th1-Th2 balancing effect of the present oligosaccharides.

As stated above, restoring and/or maintaining the Th1/Th2 balance prevents the recited allergies. Therefore, the specification provides an example that one skilled in the art would recognize as preventing the recited allergies.

Additionally, the clinical trials establish that the recited method prevents allergies. The clinical trial did not involve any measures, steps or features not described or derived from the present application. (See "Prevention of early atopic dermatitis by an infant formula supplemented with immunoactive prebiotics in low atopy risk infants," Abstract for the 27th EAACI Congress, June 7-11, 2008).

For these reasons, the specification provides guidance to make and use the recited invention without undue experimentation. Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection.

Rejection under 35 U.S.C. § 103

Claims 16, 20-39 have been rejected under 35 U.S.C. § 103 as being unpatentable over Stahl *et al.* (U.S. Publ. Pat. App. No. 2003/0022863 A1) (hereinafter referred to as "Stahl").

The invention, as recited in claim 16, is directed a method for the treatment and/or prevention of an immune system-related disorder in a mammal. The immune-system related disorder is selected from the group consisting of allergy Type 1, allergy Type 2, allergy Type 3, and allergy Type 4. The method comprises administering to the mammal a composition comprising a therapeutically effective amount of an acid oligosaccharide and a neutral oligosaccharide. The acid oligosaccharide has a degree of polymerization between 2 and 250 and is prepared from pectin or alginate. The neutral oligosaccharide is selected from the group consisting of fructans, fructooligosaccharides, indigestible dextrins, galactooligosaccharides (including transgalactooligosaccharides), xylooligosaccharides, arabinooligosaccharides, glucooligosaccharides, mannooligosaccharides, fucooliogosaccharides and mixtures thereof.

The invention, as recited in claim 27, is directed to a food composition. The food composition comprises between 5 and 50 en% lipid, between 10 and 60 en% protein, between 15 and 90 en% carbohydrate, acid oligosaccharide and neutral oligosaccharide. The acid oligosaccharide comprises at least one terminal uronic acid unit, has a degree of polymerization between 1 and 250 and is prepared from pectin or alginate. The neutral oligosaccharide is selected from the group consisting of fructans, fructooligosaccharides,

indigestible dextrins, galactooligosaccharides (including transgalactooligosaccharides), xylooligosaccharides, arabinooligosaccharides, glucooligosaccharides, mannooligosaccharides, fucooligosaccharides and mixtures thereof.

The invention, as recited in claim 30, is directed to a liquid composition. The liquid composition comprises fat, carbohydrate and protein. Per 100 ml of the liquid composition, between the liquid composition comprises 0.5 and 1 g soluble indigestible oligosaccharides, between 0.4 and 0.7 g indigestible $[galactose]_n$-glucose comprising β-linked saccharides. The "n" subscript is an integer between 1 and 60, i.e. 2, 3, 4, 5, 6, …., 59. The liquid composition further comprises between 0.01 and 0.1 g indigestible polysaccharide carbohydrate comprising a chain of at least 10 β-linked fructose units; and between 0.04 and 0.3 g acid oligosaccharides having a degree of polymerization between 1 and 250. The acid oligosaccharides are prepared from pectin or alginate.

Each of these claims relates to the discovery of restoring and maintaining the Th1/Th2 balance.

In contrast, Stalh is directed to the treatment of infections. Infections generally are defined as "the invasion of any living organism by disease-causing microorganisms, which proceed to establish themselves, multiply and produce various symptoms in the host" (see attach Oxford dictionary definition). Therefore, treating or preventing an infection is different from treating and/or preventing the recited allergies.

Stahl does not explicitly or implicitly disclose treating or preventing an inflammatory response. In paragraph [0002], Stahl states that "the interaction between the pathogens and the cells is rformed by ligan-receptor relationship." This describes a method of inhibiting and/or blocking ligan-receptor relationships. Todar's Online Textbook of Bacteriology (see attached) illustrates the role of ligand-receptor interactions in pathogen invasion. The mechanism of action underlying the method according to Stahl is therefore preventing the binding of a pathogen adhesins to receptors on host cell membranes at the site of action, the digestive tract. Thus, Stahl is directed improving the intestinal flora by anti-adhseive carbohydrates that directly and locally interfere with the binding of a pathogen to a host cell.

In contrast, the invention recited in claim 16 is improves and/or maintains a favorable Th1/Th2 balance, thus resulting in a systemic effect of maintaining or restoring proper immune system function, and inhibiting the development of a allergic reaction upon exposure to an allergen. The exposure may occur at the site where the composition is administered to the mammal, i.e. the gastrointestinal tract, or the urogenital tract and the interaction of an allergen with the immune system components may occur locally as well as systemically.

Allergies involve the interaction of an allergen with components of the immune system, in particular immunoglobulins, and a subsequent reaction of the immune system. They are not pathogens. One of ordinary skill in the art would not assume that these interactions would also be inhibited by the anti-adhesive carbohydrates disclosed in Stahl.

Since Stahl does not teach or suggest restoring or maintaining the Th1/Th2 balance, one of ordinary skill in the art would not find it obvious to treat or prevent the recited allergies. For the reasons discussed above, claims 16, 27 and 30 are patentable over Stahl. Since claims 20-26, and 32-39 depend from either claims 16, 27 or 30, these claims are likewise patentable oveer Stahl. Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection.

CONCLUSION

In addition to the remarks above, Applicants would like to call to the attention of the Patent Office that claims directed to a method for the treatment and/or prevention of an immune system-related disorder selected from the group consisting of allergy Type 1, allergy Type 2, allergy Type 3, allergy Type 4, in a related European Union patent application have been allowed.

In view of the foregoing amendments and remarks, Applicants respectfully submit that all pending claims in the instant application are patentable over the prior art and are in condition for allowance. Accordingly, reconsideration and withdrawal of the asserted rejections and a Notice of Allowance are respectfully requested.

Should the Examiner have any questions or concerns, the Examiner is invited to contact the Applicants' undersigned attorney by telephone at 412-471-8815.

Respectfully submitted,

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